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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,184	03/16/2006	Bernadette Yon-Hin	GJE-7562	2596
23557	7590	03/04/2009	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614			RIPA, BRYAN D	
		ART UNIT	PAPER NUMBER	
		4111		
		MAIL DATE		DELIVERY MODE
		03/04/2009		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/572,184	YON-HIN, BERNADETTE	
	<b>Examiner</b>	<b>Art Unit</b>	
	BRYAN D. RIPA	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>10/2/06</u> .	6) <input type="checkbox"/> Other: ____ .

## DETAILED ACTION

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

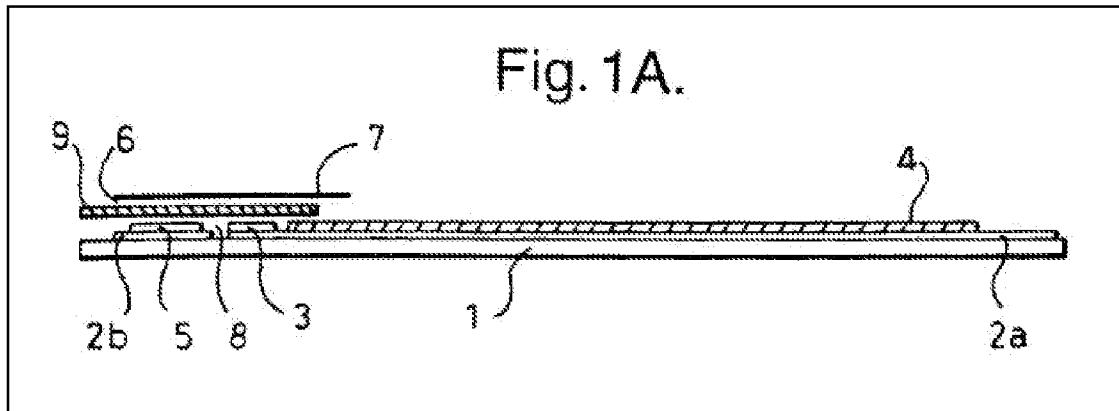
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1–5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (U.S. Pat. No. 6,436,256) (hereinafter referred to as “WILLIAMS”).

Regarding claim 1, WILLIAMS teaches a sensor comprising at least a first and second electrodes (see conductive layer 2b and analyte-specific reagent 5 comprising the first electrode; conductive layer 2a and reference electrode 3 comprising the second electrode) and a volume there between for receiving a liquid sample (see non-conducting gap 8) and which includes an agent that lyses cells (see col. 4 lines 35–38 discussing monofilament mesh 6 being coated with a lysing agent) wherein the lysing agent is in or on the surface of the first electrode (see figure 1a; col. 5 lines 45–51

showing and describing the monofilament mesh as being immediately adjacent to the electrodes). See figure 1a below.



Regarding claim 2, WILLIAMS teaches the sensor also comprising an enzyme of which glucose is a substrate (see col. 5 lines 5–9 discussing the use of the sensor to measure glucose and specifically the use of glucose dehydrogenase as the enzyme).

Regarding claim 3, WILLIAMS teaches the sensor also comprising a spreading layer over at least the first electrode (see monofilament mesh 6). See figure 1a above and ¶4 of applicant's specification.

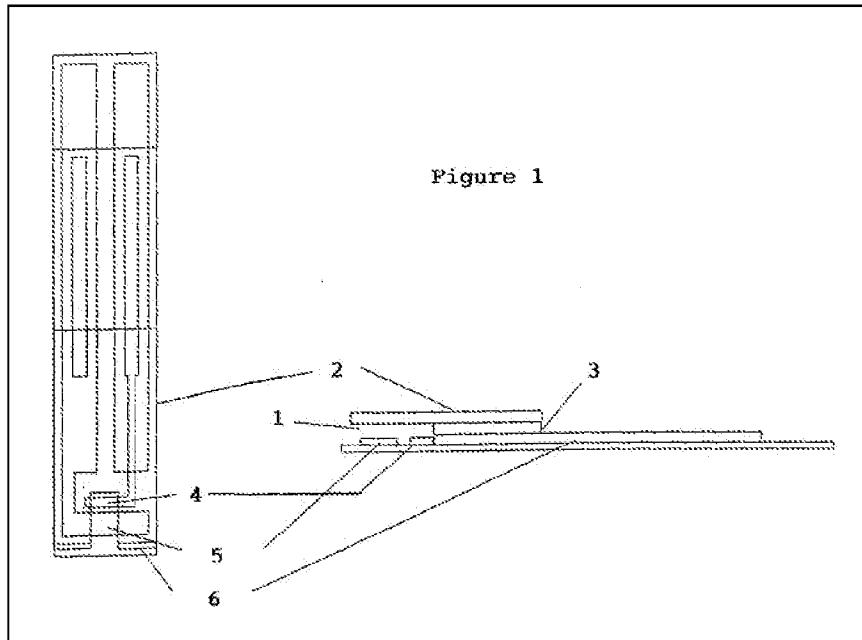
Regarding claim 4, WILLIAMS teaches the sensor wherein the lysing agent is comprised in a layer applied onto the first electrode (see col. 4 lines 35–40; col. 5 lines 45–51; figure 1a above).

Regarding claim 5, WILLIAMS teaches the sensor wherein an enzyme and/or a mediator are applied in one or more additional layers on the first electrode (see analyte-specific reagent 5; col. 3 lines 61–67)

Regarding claim 8, WILLIAMS teaches the sensor wherein the lysing agent lyses red blood cells (see col. 3 lines 7–13; col. 5 lines 5–9 discussing the reduction of the influence of hematocrit, i.e. red blood cells, by the use of a lysing agent thus implicitly teaching the lysing agent lysing red blood cells).

2. Claims 1–8 are rejected under 35 U.S.C. 102(b) as being anticipated by McCann et al. (WIPO Pub. No. 2002/14535) (hereinafter referred to as “MCCANN”).

Regarding claim 1, MCCANN teaches a sensor comprising at least a first and second electrodes (see working electrode 5 and reference/counter electrode 4) and a volume there between for receiving a liquid sample (see page 3 lines 18–21; figure 1 below) and which includes an agent that lyses cells (see page 3 lines 3–4) wherein the lysing agent is in or on the surface of the first electrode (see page 3 lines 3–4 teaching the addition of a lysing agent with the reagents; page 2 lines 20–22 teaching the reagents being deposited directly onto the electrodes; page 3 line 25 teaching the reagents being dosed onto the device). See figure 1 below.



Regarding claim 2, MCCANN teaches the sensor also comprising an enzyme of which glucose is a substrate (see page 2 lines 29–32).

Regarding claim 3, MCCANN teaches the sensor also comprising a spreading layer over at least the first electrode (see page 2 lines 20–24).

Regarding claim 4, MCCANN teaches the sensor wherein the lysing agent is comprised in a layer applied onto the first electrode (see discussion above regarding claim 1 teaching the application of a lysing agent with the reagents that would necessarily comprise a layer on the first electrode).

Regarding claim 5, MCCANN teaches the sensor wherein an enzyme and/or a mediator are applied in one or more additional layers on the first electrode (see page 4 lines 1–2 teaching the application of the reagents in a single or multiple layers).

Regarding claim 6, MCCANN teaches the sensor wherein the lysing agent is comprised in the first electrode (see discussion above with respect to claims 1).

Please note, the examiner is interpreting the phrase “the lysing agent is comprised in the first electrode” in accordance with ¶11–13 and ¶36–37 in applicant’s specification where the incorporation of the lysing agent occurs as the carbon electrode surface is dosed with a solution containing the lysing agent.

Regarding claim 7, MCCANN teaches the sensor wherein the first electrode comprises a carbon layer and on top thereof a carbon layer including the lysing agent (see discussion above with respect to claim 1 and the use of a lysing agent; page 3 lines 18–21 teaching the use of carbon; page 3 lines 27–29 teaching the carbon layer being a carbon conductor containing the redox enzyme and mediator; page 3 line 25 teaching the dosing of the reagents).

Regarding claim 8, MCCANN teaches the sensor wherein the lysing agent lyses red blood cells (see page 3 lines 3–4 discussing the reduction of the interference caused by hematocrit, i.e. red blood cells, by the use of a lysing agent thus implicitly teaching the lysing agent lysing red blood cells).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1–5 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of WILLIAMS (U.S. Pat. No. 6,436,256). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

Regarding claim 1 of the instant application, with respect to claims 1 and 4 of WILLIAMS, WILLIAMS claims a sensor comprising at least a first and second electrodes (first and second portions of the discontinuous conductive layer with the analyte-specific reagent coating on the first portion forming the first electrode and the reference electrode formed on the second portion forming the second electrode – claim

1) and a volume there between for receiving a liquid sample (non-conducting gap – claim 1) and which includes an agent that lyses cells (cell lytic agent – claim 4) wherein the lysing agent is in or on the surface of the first electrode (monofilament mesh being laid on the first electrode, i.e. the analyte-specific layer on the first portion – claim 1).

Regarding claim 2 of the instant application, with respect to claim 3 of WILLIAMS, WILLIAMS claims a sensor also comprising an enzyme of which glucose is a substrate (glucose dehydrogenase – claim 3).

Regarding claim 3 of the instant application, with respect to claim 1 of WILLIAMS, WILLIAMS claims a sensor also comprising a spreading layer over at least the first electrode (monofilament mesh - claim 1).

Regarding claim 4 of the instant application, with respect to claims 1 and 4 of WILLIAMS, WILLIAMS claims a sensor wherein the lysing agent is comprised in a layer applied onto the first electrode (monofilament mesh layer comprising the lysing agent laid on the first electrode, i.e. the analyte-specific layer on the first portion – claim 1).

Regarding claim 5 of the instant application, with respect to claims 1 and 3 of WILLIAMS, WILLIAMS claims a sensor wherein an enzyme and/or a mediator are applied in one or more additional layers on the first electrode (analyte-specific reagent layer comprising glucose dehydrogenase – claim 1).

Regarding claim 8 of the instant application, with respect to claim 4 of WILLIAMS, WILLIAMS claims a sensor wherein the lysing agent lyses red blood cells (cell lytic agent – claim 4; see col. 3 lines 7–13; col. 5 lines 5–9 discussing the reduction of the influence of hematocrit, i.e. red blood cells, by the use of the cell lytic agent thus implicitly teaching the cell lytic agent lysing red blood cells).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN D. RIPA whose telephone number is 571-270-7875. The examiner can normally be reached on Monday to Friday, 9:00 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on 571-272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. D. R./  
Examiner, Art Unit 4111

/Brian J. Sines/  
Supervisory Patent Examiner, Art Unit 4111